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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,445	01/19/2001	Edward W. Merrill	00952-8033	8881
90628 7590 02/19/2010 Massachusetts General Hospital The Genreal Hospital Corporation Perkins Cole LLP 607 Fourteenth Street, NW Washington, DC 20005				
EXAMINER				
BERMAN, SUSAN W				
ART UNIT		PAPER NUMBER		
1796				
NOTIFICATION DATE		DELIVERY MODE		
02/19/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

09/764,445

Applicant(s)

MERRILL ET AL.

Examiner

/Susan W. Berman/

Art Unit

1796

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 124-130 and 143-149 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 124-130, 143-149 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

Response to Arguments

Applicant's arguments filed 11-19-2009 have been fully considered but they are not persuasive with respect to the following issues.

Applicant's arguments regarding inherency of process steps when using a van der Graaff generator are presented to establish an effective filing date of 02-13-1996. With respect to inherent functions or properties in a disclosure the relevant passage referred to in MPEP is "To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient". Applicant has not provided any evidence to support the argument that it is inherent that UHMWPE is heated to melt after each passage through the conveyor belt of a van der Graaff generator and that several irradiation passes and heating steps are inherent to the method disclosed in Example 6. What is disclosed in Example 6, which is disclosed in SN 08/600744, filed 02-13-1996, is that the UHMWPE sample was heated in a chamber and that an electron beam was irradiated into the chamber through the thin foil at top such that a maximum dose of 20 Mrad was received 5 mm below the surface of the polymer. The heating was stopped and the sample allowed to cool to room temperature in the chamber after irradiation. Example 6 does not mention a conveyor belt, cycles of radiation or heating the UHMWPE sample to melt after each passage though a conveyor belt to apply radiation. This argument is no persuasive to establish an effective filing date of 02-13-1996 for the instant claims.

Applicant has filed, on 11-19-2009, photographs of a van der Graaff generator to further support applicant's argument of inherent features of the method of Example 6 wherein a van der Graaff generator is used to irradiate the UHMWPE sample. It is agreed that a conveyor belt is shown and that irradiation would be performed in multiple doses to reach 20 Mrads if the conveyor belt were employed. However, this is not persuasive with respect to the instant claim recitations, i.e., irradiating a fabricated article comprising UHMWPE, melting the irradiated UHMWPE, allowing the crosslinked UHMWPE to cool, and forming an implant for the crosslinked UHMWPE. These method steps are clearly disclosed in the Examples, such as Example 8, in the instant specification representing irradiation and subsequent melting.

None of claims 124, 125, 128, 130, 143 and 147 recites passages through a conveyor belt in a van der Graaf generator or heating to melt between doses of radiation. Claims 124, 125, 128, 130, 143 and 147 do not set forth a radiation dose or dose rate or sequential irradiation and heating steps. The instantly recited steps are: irradiating a fabricated article comprising UHMWPE, melting the irradiated UHMWPE, allowing the crosslinked UHMWPE to cool, and forming an implant for the crosslinked UHMWPE. These process steps are not disclosed in Example 6. Specifically, heating is stopped after irradiation in Example 6 and the sample is cooled to room temperature. These method steps were first disclosed in SN 08/726,313, filed 10-02-1996. See Example 8 in the instant specification, which first appeared in SN 08/726,313.

The dictates of MPEP 2163.02 and MPEP 2163.07 have been considered, as requested by applicant. It is not agreed that applicant, in the instant specification or in the Declarations of record, reasonably conveys to the artisan that the inventor had possession at the time of the filing of the disclosure of SN 08/600744, filed 02-13-1996, of the presently claimed subject matter. See

the discussion of Example 6 herein above. It has been established in the parent applications that the evidence for reduction to practice in the Declaration under 37 CFR 1.131 of Merrill et al filed in the present application on 11-19-2009 does not support reduction to practice of a method wherein irradiated UHMWPE is subsequently melted, as set forth in the instant claims. The evidence presented in the Declaration supports a method reduced to practice before 01-20-1995 wherein UHMWPE is melted and irradiated in the molten state. Conception of an embodiment of a combination of irradiation and melting wherein the melting is subsequent to the irradiation, as in Exhibit 1, Item C, is not evidence of reduction to practice. Thermal analysis using DSC is not evidence of reduction to practice of a method of treating UHMWPE that comprises irradiation and subsequent melting. DSC testing was disclosed as being performed to determine the melting temperature and degree of crystallization.

With regard to applicant's comments, it is agreed that the phrases "subsequent melting" and "remelting" both have the meaning heating above the melting temperature after an initial melting and irradiation. None of the instant claims recites "subsequent melting". The instant claims recite irradiating UHMWPE and heating the irradiated article to 150⁰C or above (temperatures above the melting point). There is no recitation of a first step of melting UHMWPE before the step of irradiation and the step of heating at 150⁰C or above or of following the recited heating step with another irradiation step and another heating step before cooling and forming a medical implant. The evidence for sequential heating and irradiation in the Declaration of Merrill et al, filed herein on 11-19-2009, in Experiment 2 in Exhibit 3 is evidence of reduction to practice of a method the instantly disclosed MIR method, not the instantly

disclosed IR-SM methods. Experiment 2 does not include a heating/melting step after (subsequent to) the final irradiation dose of 50 MRad.

With respect to the effective filing date of the instant claims, the issue is well settled and already clearly of record.

Claim Interpretation and Effective Filing Date

Claims 124-130 and 143-149, as amended, recite the irradiation and subsequent melting method ("IR-SM") first disclosed in SN 08/726,313, filed 10-02-1996. Thus, claims 124-130 and 143-149, wherein the irradiation step precedes the melting step, have an effective filing date of 10/02/1996 with respect to prior art disclosures. The instant claims are considered to be fully supported by the disclosure of SN 08/726,313, but not by the disclosure of SN 08/600744, filed 02-13-1996, wherein a method of irradiating UHMWPE in the molten state is disclosed but subsequent melting after irradiation is not taught. Therefore, the earliest effective filing date of the instant claims wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the 10/02/1996 filing date of SN 08/726,313.

Furthermore, claims 128-129 are not supported by the disclosure of SN 08/600,744 because SN '744 does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE. Thus claims 128-129 are not entitled to the 02-13-1996 filing date of SN '744. SN '313 does disclose the swell ratio or degree of oxidation of the disclosed UHMWPE, therefor, the effective filing date for claims 128-129 is considered to be 10/02/1996.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 124-130 and 143-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Shen et al (6,228,900, having an effective filing date of 07/09/1996). Applicant's effective filing date for a process comprising irradiation followed by melting the irradiated UHMWPE is 10/02/1996 (effective filing date of SN 08/726313). Shen et al disclose a process for preparing a medical implant comprising irradiating an UHMWPE article followed by thermal treatment by remelting and cooling, fabricating an implant and sterilizing. See column 4, lines 8-18 and 46-51, column 5, lines 29-52, column 7, lines 20-31, column 7, line 53, to column 8, line 9, column 8, lines 34-64, Example 1 and Figures 4 and 5. Since the process steps set forth in the instant claims are disclosed by Shen et al, the products resulting therefrom would be expected to have the same properties as the medical implants set forth in instant claims 126-129.

Claims 125-129 and 147-149 are rejected under 35 U.S.C. 102(e) as being anticipated by Hyon et al (6,168,626, having an effective filing date of 05/06/1996). Hyon et al disclose UHMWPE molded articles for artificial joints prepared by irradiating an UHMWPE molded

Art Unit: 1796

article and subsequently heating to the compression-deformation temperature, a temperature not less than the melting point. The treated UHMWPE is cooled and processed to provide a socket for artificial joints. See column 3, line 16, to column 5, line 13. With respect to claim 126 and 127, the products disclosed by Hyon et al would be expected to have the same properties as the instantly claimed products. The reasons are that Hyon et al disclose the process steps set forth in claim 125 and 128 and the process steps in claim 124 except for sterilizing the implant and that the properties of the product would be expected to be determined by the irradiation and compression-deformation melting steps.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-133 of copending Application No. 10/948440. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e.

melting and irradiating polyethylene, are set forth in the claims of '440 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '440. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '440 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 126-127 and 135-136 of copending Application No. 10/197209. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of '209 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of '209. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '209 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-125, 130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 127-129 of copending Application No. 10/696362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above

the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '362 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 124-130 and 143-149 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/901089. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the heated UHMWPE are set forth in the claims of '089 and in the instant claims. It would have been obvious to one skilled in the art at the time of the invention to perform the irradiation and heating steps set forth in the claims of '089 in a substantially oxygen-free atmosphere in order to avoid oxidation of the UHMWPE. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 126-129 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124,125,129,130,132-134,136, 138, and 145-152 of copending Application No. 10/197263. Although the conflicting claims are not identical, they are not patentably distinct from each other because the fabricated articles set forth in the claims of '263 are produced by irradiating and melting UHMWPE, as are

the products set forth in the instant claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB
2/8/2010

/Susan W Berman/
Primary Examiner
Art Unit 1796